15 510(k) SUMMARY

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (Per 21 CFR 807.92)

General Company Information

Name: Alveolus, Inc.
Contact: Don Canal
Vice President RA/QA

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Date Prepared: January 16, 2006

General Device Information

Product Name: ALIMAXX-E DV™ Esophageal Stent System

Classification: "Esophageal Prosthesis", Product code: ESW
21 CFR 878.3610 - Class II

Predicate Devices

Alveolus/Endoventions ALIMAXX-E Esophageal Stent System [510(k) Number K051621]

Rusch International Polyflex Stent for the Esophagus with Introducer / Delivery System [510(k) Number K030559]

Description

The Alveolus/Endoventions ALIMAXX-E DV Esophageal Stent System provides an alternate method to deploy the Alveolus/Endoventions Esophageal stent. The implantable stent for the Alveolus/Endoventions ALIMAXX-E and the subject device are the same. The ALIMAXX-E DV delivery device provides a direct visualization (DV) of the stent deployment by providing a channel inside of the

delivery device for a flexible endoscope. This channel allows the physician to directly visualize placement location, and deployment of the stent.

Intended Use (Indications)

The Alveolus/Endoventions ALIMAXX-E DV™ Esophageal Stent System is intended for maintaining esophageal lumen patency in esophageal strictures caused by intrinsic and / or extrinsic malignant tumors. The stent is also indicated for occlusion of esophageal fistulae.

Substantial Equivalence

This Notice supports the position that the Alveolus/Endoventions ALIMAXX-E DV Esophageal Stent is substantially equivalent to a number of previously cleared devices, including the Alveolus/Endoventions ALIMAXX-E Esophageal Stent System [510(k) Number K051621] and the Rusch International Polyflex Stent for the Esophagus with Introducer / Delivery System [510(k) Number K030559].

The 510(k) Notice contains summaries of physical test results for the delivery device as specified in the FDA Guidance Document for Testing Esophageal and Tracheal Prostheses (April 28, 1998).

The data presented demonstrate that the device is suitable for its indicated use.

The single-patient-use components of the ALIMAXX-E DV™ Esophageal Stent System are provided non-sterile.

Conclusions

Alveolus/Endoventions believes that the information provided establishes that similar legally marketed devices have been used for the same clinical applications as the subject device. The materials from which the Alveolus/Endoventions device is fabricated have an established history of use in clinical applications, and the devices produced by Alveolus/Endoventions have been tested in accordance with applicable FDA guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2 2006

Mr. Donald V. Canal
Vice President RA/QA
Alveolus, Inc.
9013 Perimeter Woods, Suite A
CHARLOTTE NC 28216

Re: K060239
Trade/Device Name: Alveolus/Endoventions ALIMAXX-E DV™ Esophageal Stent System
Regulation Number: 21 CFR §878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: ESW
Dated: January 27, 2006
Received: January 31, 2006

Dear Mr. Canal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

12 INTENDED USE STATEMENT

Device Name: Alveolus/Endoventions, ALIMAXX-E DV™ Esophageal Stent System

Indications For Use:

The Alveolus/Endoventions ALIMAXX-E DV™ Esophageal Stent System is intended for maintaining esophageal lumen patency in esophageal strictures caused by intrinsic and / or extrinsic malignant tumors and for occlusion of esophageal fistulae.

Prescription Use ✓ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060239